

DRAFT

12/9/02

Massachusetts Department of Public Health **Smallpox Pre-Event Vaccination Plan**

Introduction

The Massachusetts Department of Public Health (MDPH), with guidance from the Smallpox Working Group of the Statewide BT Preparedness and Response Program Advisory Committee, has developed a plan to implement Phase 1 of a 3-phase pre-event plan to protect the residents of the Commonwealth of Massachusetts against a potential smallpox bioterrorism event. Phase 1 involves vaccinating 12,000 volunteers who will participate on public health and healthcare teams. All 76 acute-care hospitals with emergency departments (EDs) in Massachusetts have been designated as sites for caring for potential smallpox cases and are included in Phase 1. In addition, 7 response teams, corresponding to the 7 bioterrorism preparedness regions, and a select group of public health and health care workers across the state will also be vaccinated.

MDPH plans to follow the recommendations of the Advisory Committee on Immunization Practices (ACIP) to stagger vaccination of healthcare workers. Therefore, the anticipated timeline for vaccination of all 12,000 workers is 10 - 12 weeks following receipt of smallpox vaccine. Other issues that may affect implementation of the smallpox vaccination program are resolution of liability and compensation issues and availability of the Pre-Event Vaccination System (PVS) and CDC educational materials.

Phase 1 of the pre-event smallpox vaccination plan provides the foundation for future smallpox vaccination activities by developing a cadre of trained and vaccinated vaccinators, hospital employees, and public health teams to respond to a potential smallpox event.

1. Organization and Management

The Massachusetts Department of Public Health (MDPH) has established several workgroups as subcommittees of the statewide BT Preparedness and Response Program Advisory Committee and Hospital Preparedness Planning Committee. The workgroups most involved in the smallpox pre-event vaccination planning are the Smallpox Workgroup, National Pharmaceutical Stockpile (NPS) Workgroup, Laboratory Workgroup, Education and Training Workgroup and the Risk Communication Workgroup. Workgroups are comprised of representatives from government agencies and non-governmental organizations including those representing hospitals, health care professionals, public safety and EMS, local public health, academicians, community health centers and other critical preparedness partners. MDPH also works very closely with the 3 federally-designated Metropolitan Medical Response Systems (MMRS) in the state (Boston, Worcester and Springfield) to ensure that their planning efforts are in concert with those at the state level. Representatives from all 3 MMRS sit on the NPS, smallpox, and hospital surge capacity workgroups and MDPH representatives participate on the working groups of the 3 MMRSs.

A. Identification of management personnel and organization charts

- **MDPH Smallpox Coordinating Unit:** Under the overall direction of the Commissioner of Public Health, 3 senior Assistant Commissioners head the coordinated development of

all assessment, planning and implementation activities that are undertaken pursuant to the HRSA and CDC bioterrorism cooperative agreements. The Assistant Commissioner for the Bureau of Health Quality Management (BHQM), Nancy Ridley, is the Principal Investigator for the HRSA Hospital Preparedness cooperative agreement. The Assistant Commissioner for the Bureau of Laboratory Sciences (BLS), Ralph Timperi, is a Co-Principal Investigator for the CDC cooperative agreement and directly oversees the Laboratory Capacity/Biological Agents component (Focus Area C) of the grant. The Assistant Commissioner for the Bureau of Communicable Disease Control (BCDC), Alfred DeMaria, is the Co-Principal Investigator for the CDC cooperative agreement. Dr. DeMaria is also the State Epidemiologist and under his oversight, the BCDC is responsible for surveillance, reporting and investigation of incidents and outbreaks of communicable diseases. The Division of Epidemiology and Immunization within BCDC will coordinate the state's Smallpox Vaccination Program, in close collaboration with other MDPH bureaus and divisions, as well as key partners outside the Department.

- **MDPH Smallpox Vaccination Program:** An organizational chart, *Massachusetts Smallpox Vaccination Program* (Attachment 1), shows the structure and location of the Smallpox Vaccination Program within MDPH. Recruitment for the positions of BT Medical Director and Smallpox Response Nurse has begun. Until these positions are filled Susan Lett, MD, Immunization Program Medical Director and Donna Lazorik, RN, Adult Immunization Coordinator, will coordinate the Massachusetts Smallpox Immunization Program.

B. Timeline for program implementation

See Attachment 2 for timeline for implementation of Phase 1 of the pre-event smallpox vaccination plan.

2. Identification of Public Health Smallpox Response Teams

A. Number and composition of teams needed

a. Statewide Public Health Smallpox Response Team:

The Statewide Public Health Smallpox Response Team of approximately 60 – 75 MDPH employees and staff from the State Medical Examiner's Office will assist the Regional Smallpox Response Teams in conducting investigations and outbreak control for the initial cases in a smallpox event. Under the direction of the Commissioner of Public Health, the statewide team will consist of:

Assistant Commissioner for the CD Bureau/State Epidemiologist
Assistant Commissioner for the Bureau of Health Quality Management
Assistant Commissioner for the Bureau of Laboratory Sciences
State Medical Examiner's Office
Division Director, Division of Epidemiology and Immunization
Director, Infectious Disease Laboratory
Medical Director, Immunization Program
Program Manager, Immunization Program
Vaccine Manager, Immunization Program

Nursing Supervisor, Immunization Program
 Adult Immunization Coordinator, Immunization Program
 Epidemiology Coordinator, Immunization Program
 Medical Director, Epidemiology Program
 BT Coordinator, Epidemiology Program
 Program Manager, Epidemiology Program
 Emergency Preparedness Coordinator
 BT Public Health Nursing Advisor
 Smallpox Response Nurse
 BT Medical Consultant
 Office of Emergency Medical Services
 Medical Director, Hospital Preparedness
 Local Public Health Preparedness Coordinator
 BCDC Local Health Coordinator
 Director, Drug Control Program
 NPS Statewide and Regional Coordinators
 NPS Statewide Manager
 10 MDPH laboratory staff
 15-20 MDPH nurses
 20 MDPH Immunization Program and Epidemiology Program epidemiologists

b. Regional Smallpox Response Teams

The Commonwealth of Massachusetts is divided into 7 regions for the purposes of bioterrorism preparedness planning and response. One Smallpox Response Team will be established for each of the 7 regions. The Teams will investigate any suspect case of smallpox in the community and mitigate the hazard by closing off access to the area, isolating contacts of the suspect case until they can be interviewed, and safely transporting the suspect case to the hospital.

The Regional Teams will be recruited with the assistance of the Statewide BT Preparedness and Response Program Advisory Committee, the MDPH Office of Emergency Medical Services, the State Fire Marshall's Office, the Massachusetts Health Officers Association and the Massachusetts Association of Public Health Nurses. Under the direction of the Regional Bioterrorism Coordinator, each of the 7 teams will include a total of 150 personnel, who will be available 24 hours/day:

The Smallpox Workgroup has identified how teams would be organized and deployed.

- Response team composition by position title and agency affiliation – 7 response teams will consist of a multidisciplinary group of 17 individuals drawn from 150 pre-designated volunteers for each team (2-4 first responders, 2 medical professionals (including at least 1 physician), 2 epidemiologists, a laboratory professional, 4 law enforcement officials and 4 local officials). The teams will provide the following functions: patient care and transport, specimen collection and transport, medical diagnosis, site security, control of the environment, contact investigation, and event

management. To fully staff teams, a total of 1,050 individuals will be vaccinated and trained.

- Response team functional capacity – teams will be constituted to mobilize a full complement of 17 to respond to the site of a highly suspect or confirmed smallpox case anywhere within their region within one to two hours. Response to a suspect case will be coordinated with neighboring states when appropriate.

c. Public health nurses/vaccinators and emergency medical personnel

In addition, 3,000 public health nurses, including municipal nurses, school nurses and visiting nurses, and emergency technicians and paramedics from across the state will be trained and vaccinated to build capacity for future smallpox vaccination activities. These vaccinated and trained nurses will form the core of a cadre of trained health care providers who will be ready to implement mass smallpox vaccination clinics in the event of a bioterrorism attack. These nurses will be recruited with assistance of the Statewide BT Preparedness and Response Program Advisory Committee, the Massachusetts Nurses Association, the MDPH Office for School Health, the Massachusetts Association of School Nurses and the Massachusetts Association of Public Health Nurses. Emergency technicians and paramedics will also be recruited through the Statewide BT Preparedness and Response Program Advisory Committee, as well as through the MDPH Office of Emergency Medical Services and through their employers.

B. Timeline for selection and vaccination of individual team members

A Scope of Service has been developed for a vendor(s) to conduct vaccination of non-hospital employees and an emergency waiver to the bidding process is being sought to facilitate the establishment of a contract. Meetings with the relevant unions and professional associations to provide information, address their concerns and solicit their assistance in identifying and recruiting individuals for the Response Teams has begun and will continue. Screening and education of volunteers will begin the week of January 5, with vaccination beginning the week of January 19, contingent upon receipt of the vaccine, resolution of liability and compensation issues, and availability of the PVS and CDC educational materials.

3. Identification of Healthcare Smallpox Response Teams

MDPH is working very closely with the Statewide HRSA Hospital Preparedness Planning Committee and the Massachusetts Hospital Association to develop a system and protocols for safe vaccination of multidisciplinary teams at each of the 76 acute care hospitals with emergency departments in the Commonwealth. A health care systems approach is being encouraged whereby one hospital in each system will be responsible for implementing a screening, education, vaccination and follow-up program for all hospitals in the system. There are approximately 16 systems covering most of the hospitals, with the remaining hospitals being unaffiliated. Small unaffiliated hospitals will be encouraged to develop agreements with larger hospitals to vaccinate their staff, or may have their employees vaccinated at the vendor-run clinics.

A letter from the Massachusetts Hospital Association was faxed to all hospitals on November 26 outlining the plan and asking each hospital to identify a smallpox preparedness coordinator, as well as a pharmacy contact and an information technology contact. These

names and contact information are being compiled into a data base at MDPH. The letter also asked each hospital to review the function and operation of their negative-pressure isolation rooms and to consider further the make-up of internal smallpox teams and identify staff for smallpox vaccination, reinforcing that vaccination will be voluntary. In addition, a conference call was held between the Commissioner and assistant Commissioners of Public Health and the CEOs and Disaster Preparedness Coordinators of all 76 hospitals.

A. Estimated number of hospitals and health care response teams expected to participate

All of the 76 acute care hospitals that have emergency departments are expected to participate.

B. Policy for vaccination of hospital employees

a. Pre-program education

Each hospital, with assistance from MDPH, will be responsible for identifying and recruiting appropriate and eligible candidates for pre-event smallpox vaccination and coordinating their eligible candidate list with MDPH. Each hospital will be responsible for educating all potential candidates at their facility, using CDC-developed materials and providing each potential candidate with the CDC document *Information About Smallpox Vaccination for Medical and Public Health Response Personnel Considering Smallpox Pre-Event Vaccination*. Each hospital will provide referrals for persons who request HIV or pregnancy testing to local laboratories or confidential counseling sites. The vendor-run clinics will provide pre-program education and referral for the Response Teams.

b. Screening

Each vaccination clinic site (vaccinating hospitals or vendor-run clinics) will be responsible for screening candidates for vaccination, including completion and review of medical history forms, reinforcement of adverse events education, answering patient questions and obtaining patient consent.

c. Adverse event evaluation and treatment

For a detailed description of hospital responsibilities for evaluation of adverse events, see *Section 8: Vaccine safety monitoring, reporting, treatment and patient referral* below.

d. Daily vaccination site management

Each hospital will be responsible for training and assigning sufficient staff to monitor the vaccination site of all their employees at the beginning of each of their shifts until the site is healed. These personnel also will be responsible for vaccination site dressing changes as necessary and for reinforcing infection control techniques for all vaccinees. For public health nurses, a nurse at each facility (school, health department, visiting nurse association, etc.) will be responsible for monitoring the vaccination sites of the other nurses at that facility. In those situations where there is only one nurse, that nurse will be responsible for monitoring her/his own vaccination site.

e. Evaluation of vaccination takes

Each hospital will be responsible for validating the vaccine take response 6 – 8 days after the vaccination is given and recording the take reading both on paper (forms and patient vaccination card) and in the Pre-Event Vaccination System (PVS). The hospital will refer vaccinees with a negative take to the vaccination clinic site for revaccination. The vendor-run clinics will be responsible for evaluating and documenting the vaccination take for the members of the Response Teams. Documentation of the takes will be entered into the Pre-Event Vaccination System (PVS) or other CDC-certified data management system.

C. Estimated number and occupational types of healthcare personnel expected to be vaccinated

Each hospital will be expected to determine the exact composition of their health care teams. MDPH will provide the hospitals with guidelines adapted from those developed by the State of Connecticut. This works out to an average of 100 health care workers per hospital, for a total of approximately 7,500 – 8,000 hospital employees in Massachusetts. MDPH is in the process of soliciting comments on draft guidance that will be provided to hospitals in identifying their healthcare teams. The draft guidance is as follows:

Healthcare Worker Position	Approximate Number of FTEs for Each Hospital
Emergency Department	
ED nurse	50 % of all (average 20/hospital)
ED physician/physician assistant	100% of all (average 15/hospital)
ED clerks	5
Total ED	Variable depending on size of staff (average 40/hospital ED)
Inpatient	
ICU/med-surg/pedi nurses	25
Occupational health nurses	5
Dialysis nurse	1
Adult intensivist/pulmonologist	5
Pediatrician	1
Infectious Disease Specialist	1
Surgeon	1
House staff	5
Respiratory tech	5
Radiology tech	2
Phlebotomist	1
Housekeeping	2
Security	5
Engineering/HVAC expert	1
Total Inpatient	60/hospital
Total ED and Inpatient	Approx. 100/each hospital with substantial variation depending on size of ED

Regional teams of consultant specialists:

Hospitals and professional specialty associations will be asked to help identify physicians with expertise in the following areas to serve as consultants to hospitals and smallpox vaccination clinics on screening and adverse event issues, as well as diagnosis and treatment of smallpox cases should they occur. These physicians will also be vaccinated as part of the healthcare response teams.

- Dermatology
- Immunology
- Infectious Disease
- Neurology
- Ophthalmology
- Pathology
- Urology

D. Timeline for selection of hospitals and individual health care workers and vaccination of the health care response teams

It is anticipated that all 76 acute care hospitals with emergency departments in the Commonwealth will participate. By December 7, MDPH will provide hospitals with criteria and other guidance for identifying appropriate and eligible candidates. The selection of candidates will be finalized by December 28 and education and screening will begin by January 11. Vaccination of the healthcare response teams will begin January 19, contingent upon receipt of the vaccine.

4. Selection of Clinic sites and Vaccination Teams

A. Number and tentative location of clinic sites

MDPH is currently conducting site visits to 4 state hospitals (in Boston, the northeast, the southeast and western region of the state) as potential sites for the vendor-run smallpox vaccination clinics. In addition, it is expected that a number of the larger hospitals will be responsible for vaccinating hospital employees from their own and affiliated facilities.

The City of Boston is planning a collaborative approach between the Boston Public Health Commission and a partnering hospital in the city to establish one team to vaccinate hospital health care teams and the public health response team in the city. MDPH is working with the Massachusetts Hospital Association to encourage the establishment of similar regional vaccination teams for hospital employees in other parts of the state.

B. Timeline for selection of clinic sites and clinic vaccination teams

Selection of clinic sites will be finalized by January 4. Screening of vaccination teams, including vaccinators, medical evaluators and other hospital staff responsible for site care, infection control, validation of vaccination take and follow-up for adverse events will take place January 5 - 12. A core group of approximately 100 vaccinators will be trained by January 11, and vaccinated by January 11 if smallpox vaccine is available.

C. Plan for training clinic teams and for providing supervision, management and evaluation of the clinic and clinic team members

The initial core group of vaccinators will be made up of physicians and nurses from MDPH, as well as representatives from the Massachusetts Nurses Association, the Massachusetts School Nurses Association and the Massachusetts Association of Public Health Nurses. This core group of vaccinators will be responsible for training and vaccinating the vaccination teams at the hospitals and clinic sites. MDPH will contract with occupational health systems in the state that have experience with smallpox vaccination to have them vaccinate and train the core group of vaccinators. This vendor(s) will likely be responsible for the vendor-run clinics as well.

Training of vaccination teams will be a major responsibility of the vendor(s) and hospitals involved with this initiative. In Phase I, we project that in addition to approximately 8,000 hospital workers and 1,000 response team members, 3,000 local public health nurses and other professionals will be trained to administer smallpox vaccine and carry out the ancillary duties associated with its administration, through the activities of the vendor(s). Emergency medical technicians and paramedics will be trained and vaccinated to provide additional support for vaccination effort emergency management and to participate on response teams.

Each vaccination clinic site will have one person designated as the clinic supervisor responsible for supervision, management of all clinic activities and evaluation of clinic team members. All clinic sites will receive site visits by the MDPH Smallpox Vaccination Program staff to support and evaluate clinic operations.

D. Days and hours of clinic operations

Clinic hours will be determined by the hospitals running the clinics. In addition to the hospital-based clinics, there will be 20 vendor based-clinics held over 10 weeks (2 clinics/week statewide). These clinics will rotate among 4 sites in different regions of the state. Each clinic will be 8 hours long and will include at least one weekend day in each region. Each of the 20 clinics will process 150 vaccinees for a total of 3,000 vaccinees in 10 weeks.

E. Estimated number of clinic personnel needed

These clinics will be responsible for screening, vaccinating, evaluating vaccination takes and providing follow-up on adverse events for 3,000 vaccinees. Each clinic will be staffed as follows in order to process 150 vaccinees in 8 hours:

- 1 clinic manager
- 1 appointment scheduler
- 5 – 6 medical screeners
- 2 vaccinators
- 2 assistant vaccinators
- 2 people to manage and monitor clinic flow
- 2 data entry staff

All clinics will have, at a minimum, telephone access to medical consultants (Physician Evaluators) for questions and issues regarding screening, vaccination, evaluation of vaccination takes, and follow-up and treatment of vaccination side effects and adverse events.

Clinic security at both hospital and vendor-run clinics will be managed by the sites at which the clinics are held.

5. Scheduling

A. Estimated number of persons who will be vaccinate each week

We estimate that a total of 12,000 people will be vaccinated over 10 weeks (1,200 people/week total for all the clinics).

B. Strategy for scheduling vaccinations of hospital and response teams

Hospitals vaccinating their own staff will schedule their teams for education, screening, vaccination, vaccination site checks and vaccination take evaluation, vaccinating 10% of the members of their teams each week for 10 weeks. The scheduling of vaccination of the response teams will be coordinated between the MDPH Regional Offices and the vendor(s) running the clinics and will occur over 10 weeks.

7. Clinic Operations and Management

Phase 1 of pre-event smallpox vaccination will take place in two types of clinics. The first type of clinic will be hospital-based, where multidisciplinary teams of 100 employees from the 76 hospitals will be vaccinated. The second type of clinic will consist of 4 vendor-run regional clinics to be held at state hospitals. Members of the 7 regional smallpox response

teams, approximately 3000 paramedics, EMTs, public safety personnel, medical consultants, public health nurses and epidemiologists will be vaccinated at these sites.

Staff at both types of clinics will be responsible for essential clinic functions including:

- establishing patient flow
- record keeping
- educating and screening potential vaccinees
- clinic security
- ensuring adequate education materials, forms, and other supplies
- stocking of medical supplies
- worker safety
- obtaining consent
- vaccine handling
- vaccination
- acute medical reaction management
- data collection/entry into the information system
- vaccine accountability
- post vaccination wound management
- waste disposal
- advice on adverse events and reporting
- completing the vaccinee's vaccination card
- evaluating the vaccine take

Screening, vaccine administration, and follow-up will be conducted in accordance with ACIP, HICPAC and CDC guidelines. The MDPH will work with vendors overseeing the vaccination sites and hospitals to ensure appropriate disposal of medical waste generated at the clinics.

A. Description of the process for ensuring adequate screening of potential vaccinees

At both hospital and vendor-run clinics, all potential candidates for vaccination will undergo the following process:

- a. General informational sessions will be open to all potential vaccination candidates to explain the pre-event smallpox vaccination program. Potential candidates will receive an information packet prepared by the CDC that contains:
 - the video script;
 - the document “*Information about Smallpox Vaccination for Medical and Public Health Response Teams Personnel Considering Smallpox Pre-Event Vaccination*”;
 - information statements on pregnancy, skin conditions, and immune system problems;
 - the Smallpox Vaccine Information Statement (VIS);
 - self-screening form;
 - expanded vaccination site care card; and
 - proof of vaccination card.
- b. Potential candidates will view the video, which contains the essential elements of informed consent as promulgated in 12 CFR 50.25. This video viewing will be witnessed to comply with FDA regulations for the oral presentation of consent information. The

script of the video is included in a packet and will include, at a minimum, English presentations and Spanish language translations. Additional translations may be needed to address specific populations in the Commonwealth.

c. Potential candidates will complete the self-screening form.

d. A screening nurse will review the candidate's screening form for self-identified contraindications for the individual and household contacts and address any issues or questions relating to the decision to be vaccinated. If the individual has no self-identified contraindications or questions, they will be allowed to proceed with vaccination. All vaccinees will be referred to confidential or anonymous HIV counseling and testing if they feel they are at risk. Women who are unsure about their pregnancy status will be counseled to take a home pregnancy test on the morning they are scheduled to be vaccinated and to not get vaccinated if they are pregnant or want to become pregnant in the 4 weeks following vaccination. Any unresolved questions or issues will be referred to a medical consultant for further discussion if the candidate is still interested in becoming vaccinated.

Since vaccination is fully voluntary, no person declining to be vaccinated will be compelled to state their reason for declining.

e. When the candidate presents for smallpox vaccination, the vaccination nurse will review the screening form with the vaccinee. The vaccinee will also be offered the opportunity to ask questions prior to being vaccinated.

B. Plans to ensure clinics have adequate supplies and equipment and educational and screening materials

a. Supplies and equipment

Both types of clinics, hospital staff clinics and vendor-run clinics, will each designate a Clinic Supply Manager, whose responsibilities will include overseeing all clinic supply and equipment needs; tracking vaccine supply/lot numbers, distribution, and wastage; and re-supplying vaccination stations, as needed. All clinics will keep, at a minimum, a 2-day supply of materials on hand. All clinics, both hospital- and vendor-run, will be responsible for acquiring all supplies necessary for running the clinics. MDPH will supply the clinics only with the smallpox vaccine packets as they are shipped from CDC, as well as CDC educational and screening materials.

b. Educational and screening materials

The clinic supply manager will ensure the availability of all necessary education and screening materials. All clinics, at both hospital staff and vendor-run clinics, will receive an initial distribution of educational and screening materials from the Massachusetts Department of Public Health and will keep a 2-day supply of materials on hand. All clinics will be equipped with a computer with internet access to download relevant educational and screening materials from the CDC website, a photocopy machine to make multiple copies of these materials, and a video monitor to allow vaccinees to view the video.

C. A timeline for implementing operations

All screening and training activities will occur according to the following timeline. Any vaccination activities will be dependent on the following contingencies:

- Receipt of the vaccine
- Resolution of liability and compensation issues
- Availability of a functioning PVS or other CDC-certified data management system
- Availability of finalized screening materials
- Availability of CDC training and education materials

December 15 – January 4

- Finalize sites for vaccination clinics
- Begin certifying hospitals and vendor-run clinic sites for receipt of smallpox vaccine
- Provide hospitals and vendor-run clinics with screening and vaccinee education materials

January 5 – 11

- Train and vaccinate core group of vaccinators
- Finish certification of sites that will store vaccine
- Assuming availability of CDC's Pre-Event Vaccination System (PVS) or other CDC-certified data management system, begin training hospital and vendor-based clinic staff on the use of the system
- Hospitals and vendor-based clinics begin screening and education of vaccinees

January 12 – 18

- Train and vaccinate multidisciplinary vaccination teams
- Train and vaccinate vendor-based clinic staff
- Continue screening hospital team

January 19 – 25

- Begin screening response teams
- Begin vaccinating hospital employees
- Continue vaccinating public health teams and hospital employees

January 26 – February 1

- Continue vaccinating hospital employees at the rate of 10% of vaccination candidates from each hospital per week (or 20% every 2 weeks) for 10 weeks
- Begin vaccinating response teams

February 2 – March 31

- Continue to vaccinate hospital employees and response teams

8. Vaccine Safety Monitoring, Reporting, Treatment and Patient Referral

All of MDPH's smallpox vaccine safety monitoring/reporting and patient treatment/referral plans will be based on CDC's Smallpox Immunization Safety System (SISS) guidelines. To collect data and assign a Patient Vaccination Number (PVN), we will utilize either CDC's Pre-Event Smallpox System (PVS) or a CDC-certified commercially available and compatible system. Any adverse events identified will be reported via the Vaccine Adverse Event reporting System (VAERS). All protocols will be developed in accordance with the guidance in Annex 4 of CDC's Supplemental Guidance for Planning and Implementing the NSVP, ACIP recommendations and other pertinent CDC documents.

A. Individuals responsible for coordinating vaccine safety monitoring, reporting, treatment and patient referral

Adverse Event Response Team

The Medical Director of the Immunization Program (Susan Lett) will be the main coordinator for vaccine safety monitoring, reporting, treatment and patient referral.

Core members of the adverse events response team - The Assistant Commissioner for the Bureau of Communicable Disease Control (Alfred DeMaria, Jr) will head the adverse event response team at MDPH, which will include the Medical Director of the Immunization Program (Susan Lett), the Medical Director for Hospital Preparedness (Jonathan Burstein) and the Medical Director of the Epidemiology Program (Bela Matyas). Members from other agencies include: the Medical Director of Communicable Disease Control (Anita Barry) and Medical Consultant (Tara McCarthy) at the Boston Public Health Commission; the Medical Director of the Clinical Immunization Safety Assessment Center at Boston University (Colin Marchant) and key members from the Massachusetts Infectious Disease Society (MIDS). We are in the process of identifying other pertinent medical specialists.

The core members will serve as a resource to a wider network of specialists who are affiliated with:

- hospital networks who will be vaccinating hospital workers (hospitals are being urged to collaborate within their networks to both organize clinics and develop a team of specialists who can respond regionally to adverse events); and
- vendors who will be vaccinating the out-of hospital response team members.

B. Plan to provide for adverse event monitoring, reporting, treatment and referral

- **Consultation and referral** - Hospital vaccination centers and the vendor-run centers will both be developing protocols to ensure proper patient screening and referrals for further consultation, if necessary. Vaccination centers will identify teams of infectious disease specialists, dermatologists, ophthalmologists, nephrologists, neurologists, allergists/immunologists and other pertinent medical specialists. They will be available for consultation 24 hours per day/7 days per week (24/7).
- **Ensuring vaccine safety at the vaccination centers** - Vaccination centers will need to identify a medical director who will be responsible for ensuring that pertinent staff have received all proscribed training. Education of involved staff will include a complete review of the current CDC and ACIP guidelines and algorithms. Such training will include:
 - proper screening for contraindications and precautions
 - vaccine administration
 - treatment immediate hypersensitivity and other adverse events
 - education of vaccinees about site care, vaccine take, vaccine adverse events and what to do if they have an adverse event
 - ensuring vaccinees have materials needed for site care

- knowledge of the SIIS, PVS and VAERS data recording requirements and reporting protocols.

See section 9: *Training and Education* below for more information on these efforts.

- **Protocols for use of VIG and/or cidofovir** - MDPH will develop protocols for VIG and/or cidofovir for the treatment of complications from smallpox vaccination, based on the indications outlined in the ACIP/CDC recommendations.
- The core adverse response teams will be on call 24/7 to consult with the network of specialists about the correct indications for VIG/cidofovir. The core team will contact CDC when indicated to request release of these products.
- Treating facilities must agree to follow the Investigational New Drug Protocols (IND) and complete the necessary IND paperwork and reporting requirements.
- **Hotline coordination** - There is currently a hotline established within the Division of Epidemiology and Immunization to respond to questions from the public and providers, which is accessible 24/7. There is also an automated hotline capable of handling large volumes of calls which can be activated as needed and has been activated in the past to deal with certain acute situations (West Nile virus, anthrax in fall of 2001, etc.). If needed, the Division's Hotline can connect to or supplement the national hotline number.
- **Smallpox education initiative for all health care providers** - Vaccinees may not present back to their designated vaccination centers, referral networks or work sites for evaluation of problems relating to smallpox vaccination. Therefore, we are planning an educational campaign directed at all health care providers in the state to increase basic understanding of postvaccination evaluation, referral and reporting of adverse events following vaccination. This initiative will include making sure they are aware of the hotline number, referral physician network and VAERS. In addition, the state's Health Alert Network (HAN) and immunization registry, which are both under development, will become important mechanisms for communicating with providers. We will also provide education through professional organizations, newsletters and advisories.

9. Training and Education

MDPH will ensure that all public health and medical professionals receive general education on the components of the smallpox vaccination plan with guidance from the state Bioterrorism Training and Education Work Group, and the Long Distance Learning Coordinator. MDPH will use a variety of methods, venues, and materials, relying heavily on the CDC's training and educational materials, including live satellite broadcasts, audiocasts, videotapes, CD ROMS, web-based and printed materials. MDPH will mail all public health and medical professionals the CDC's Clinician Smallpox Education Packet, as well as a description of the components of the Commonwealth's pre-event smallpox vaccination plan. The mailing will include copies of the CDC's *Smallpox Vaccination: Vaccination Methods and Reactions* pamphlet and the *Evaluating Patients for Smallpox: Acute, Generalized, Vesicular, or Pustular Rash Illness Protocol* poster to assist them with recognizing reactions to smallpox vaccine.

MDPH will contract with vendor(s) who will provide occupational health physicians and nurses with expertise in the administration of smallpox vaccine. The vendor(s) have

developed curricula and train-the-trainer protocols that cover all aspects of smallpox vaccine administration, including:

- record keeping,
- educating and screening potential vaccinees,
- obtaining consent,
- vaccine handling,
- vaccination,
- acute medical reaction management,
- post vaccination site care and infection control,
- advice on adverse events and reporting,
- completing the vaccinee's vaccination card, and
- evaluating for vaccine take.

MDPH will require that all vaccination clinic staff view a video of the CDC satellite broadcast: *Bioterrorism Update: Smallpox Preparedness*. All members of the vaccination teams will be certified following completion of all required elements of the training. The specific curriculum will be developed by the vendor(s) with input from MDPH.

MDPH is hiring regional health educators to cover each of the 7 BT regions in the Commonwealth. These regional health educators will help provide education to the general public about the smallpox vaccination plan.

A. Venues for training

The vendor(s) and the MDPH regional health educators will arrange training venues for smallpox vaccination clinic staff.

B. Specific personnel to be trained

All smallpox vaccination clinic staff will be trained, including vaccinators, screening personnel, medical evaluators, and vaccination site monitors.

C. A timeline for implementation

December 5 – 6: CDC's *Bioterrorism Update: Smallpox Preparedness* satellite broadcast

December 6 – January 5: Contract with vendor(s) to provide smallpox vaccination clinic staff training

January 5 – 11: Train core group of vaccinators ,

January 12 – 18: Train multidisciplinary vaccination teams

January 18 – 21: Mail educational materials to public health and medical professionals

10. Data Management

A. Contact Information for Data Information Team

In coordination and collaboration with CDC, state, local and clinic team members, the Data Information Team will provide technical support, training, implementation, and maintenance of the PVS and other related IT systems. Below is a list of the team members. These individuals will also determine the functional requirements of the state and evaluate the functionality of PVS and CDC-certified third party systems, as available.

Name	Position	Telephone	e-mail
James Daniel	IT Program Manager	617-983-6808	James.Daniel@state.ma.us
Lily Parsi	NEDSS System Analyst	617-983-6800	Lily.Parsi@state.ma.us
John Schaeffer	HAN Systems Analyst	617-983-6800	John.Schaeffer@state.ma.us
Gillian Haney	Surveillance Program Manager	617-983-6800	Gillian.Haney@state.ma.us
Michele Jara	NEDSS Coordinator	617-983-6800	Michele.Jara@state.ma.us
Steven Levy	Project Director, State Registry System	617-983-6800	Steven.Levy@state.ma.us

B. Data Management Plan

MDPH will use the PVS with named data, as collection of these data will be valuable to hospitals and other public health partners.

While using PVS, MDPH will support the IT and data entry needs of hospitals to ensure compliance with CDC requirements. Because some hospitals may not have the technical capability or staff to enter data via web-based forms, centralization of Batch ID generation and data entry of PVS and VAERS forms may be necessary.

Centralization of data management within regions of the state will be considered on a case-by-case basis. Within the Boston metro region, MDPH will coordinate efforts with Boston Public Health Commission. Support for regional centralized data management will occur through temporary personnel and will be funded through current BT cooperative agreement funds. Quality control and quality assurance procedures will be put in place to monitor any centralized Batch ID generation or data entry of PVS and VAERS forms.

Once CDC certifies third party systems, MDPH will evaluate these systems to determine whether they meet the functional requirements of MDPH. Specifically, MDPH plans to investigate systems that can be implemented as modules of our current Health Alert Network or planned State Immunization Registry.

Ideally, the system will handle vaccine inventory and management, pre-screening of patients, tracking of vaccinations and takes (including all applicable reports), and will include data transfer to PVS, VAERS and the planned state immunization registry.

11. Communications

A. Point of contact responsible for communications associated with this activity

The point of contact for this activity is Donna Lazorik, RN, Adult Immunization Coordinator and Acting Smallpox Vaccination Program Coordinator (617-983-6821).

B. Critical communication issues

The CDC BT Preparedness and Response Program Advisory Committee and HRSA Hospital Preparedness Planning Committee, Smallpox Work Group, are fully engaged in the effort to ensure that all medical and public health professionals in the state understand the purpose of the pre-event smallpox vaccination program. The professional organizations are also active participants in this effort. MDPH is making use of its extensive networks and list serves to ensure that the information is available in a variety of formats to all health care providers and public health workers. MDPH will also do a mailing to health care providers in the state, which will include a description of the pre-event vaccination program, the CDC pamphlet on Smallpox Vaccination and the CDC smallpox poster.

MDPH will also work with the Risk Communication Work Group to prepare the general public for the initiation of smallpox vaccination in their communities by providing them with information and addressing their concerns via a variety of media, including a website and press releases.

Reporting to CDC

The MDPH Smallpox Vaccination Program Coordinator will submit semi-weekly reports to CDC on each Monday and Thursday throughout the vaccination program using the CDC *Smallpox Preparedness Vaccination Program Progress Report Form*.